Materials Submitted to NIH
from Children's Memorial Hospital
Submission #2009-ACD-009

NOTE: Working Group is still considering cell lines CM-1, 5, 8, 11, 12, 13, 14, and 16, so those lines are not being put forward for ACD consideration at this time. Information specific to those lines, including clinic information, has been removed from this document.

NOTE: Duplicative information in the submission is not included.

(1)

hESC Registry Application Database

Detailed Listing for Request #: 2009-ACD-009
November 16, 2010

hESC Registry Application Search Results

Request #: 2009-ACD-009
Status: Pending

Review: ACD

Assurance: Yes (Section II(B))
Certification: Yes
Authority: Yes

Cell Lines: 11
Available: 11

Previous #:
2009-DRAFT-007

Email
Edit
Delete
Switch to ADM

Organization: Children's Memorial Hospital
Org Address: 2300 Children's Plaza, Box 205, Chicago, IL, 60614-3394
DUNS: 074438755 **Grant Number(s):**
Signing Official (SO): Harmony Maple / 773-755-6334 / HMaple@childrensmemorial.org
Submitter of Request: Vasil Galat / 773-755-6598 / v-galat@northwestern.edu
Submitter Comments: Expression databases established on hESC lines including CM 7 and CM 14 are used as preliminary data for iPSCs validation GRANT10279457 (HL100168-01)

Line #1: CM-1
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/
Provider Restrictions: None

NIH Restrictions:

Additional Information:

not being presented at 12/09/10 meeting

Line #2: CM-2
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/
Provider Restrictions: None

NIH Restrictions:

Additional Information:

Line #3: CM-5
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes

not being presented 12/09/2010

(2)

Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/
Provider Restrictions: None

NIH Restrictions:

Additional Information:

Line #4: CM-6
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/
Provider Restrictions: None

NIH Restrictions:

Additional Information:

Line #5: CM-7
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/
Provider Restrictions: None

NIH Restrictions:

Additional Information:

Line #6: CM-8
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/

not being presented 12/09/10

(3)

Provider Restrictions: None

NIH Restrictions: not being presented 12/09/10

Additional Information:

Line #7: CM-11
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/
Provider Restrictions: None

NIH Restrictions:

Additional Information:

Line #8: CM-12
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/
Provider Restrictions: None

NIH Restrictions:

Additional Information:

Line #9: CM-13
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/
Provider Restrictions: None

NIH Restrictions:

Additional Information:

4

Line #10: CM-14
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/
Provider Restrictions: None

not born's presented 12/09/10

NIH Restrictions:

Additional Information:

Line #11: CM-16
NIH Approval #:
Available: Yes
Embryo from U.S.: Yes
Embryo Donated in Year(s):
Provider Name: Vasil Galat, Ph.D., HCLD. CMRC iPS and Human Stem Cell Core Facility. Children's Memorial Hospital
Provider Phone: 773-755-6598
Provider Email: v-galat@northwestern.edu
Provider URL: http://www.childrensmrc.org/stemcellcore/
Provider Restrictions: None

NIH Restrictions:

Additional Information:

Supporting Documents:
Document 1: (PDF - 11/17/2009) Summary
Document 2: (PDF - 11/17/2009) CMRC IRB decision (exempt)
Document 3: (PDF - 11/17/2009) NUCHSCR Approval
Document 4: (PDF - 11/17/2009) Fertility Centers Letters
Document 5: (PDF - 09/29/2010) Sample Consent Forms_redacted
Document 6: (PDF - 11/18/2009) SO Approval Letter

Administrative Comments: November 23, 2009 SO certification buttons checked by E. Gadbois per SO letter.

January 10, 2010 response letter from Vasil Galat on providing copies of informed consent for particular embryo donation for research.

February 17 2010 response letter from WG to CMRC uploaded by E. Gadbois

July 8 Email Questions to submitter uploaded by D. Hannemann on 12 July 2010

(5)

July 9 Email Response from submitter uploaded by D. Hannemann on 12 July 2010

IRB Exemption Letter from WIH uploaded by D. Hannemann on 12 July 2010

[redacted] Statement on embryo transfer uploaded by D. Hannemann on 12 July 2010

July 15 Email Response from submitter uploaded by D. Hannemann on 15 July 2010

July 27 Email Response from submitter uploaded by D. Hannemann on 28 July 2010

Frozen embryo donation consents uploaded by D. Hannemann on 28 July 2010

Fresh embryo donation consent uploaded by D. Hannemann on 28 July 2010

ESC Consent uploaded by D. Hannemann on 28 July 2010

July 28 Email from Submitter uploaded by D. Hannemann on 28 July 2010

IVF Clinic Attestation uploaded by D. Hannemann on 28 July 2010

Redacted version of MFC Informed Consent (Doc 5) by D. Hannemann on 29 Sept 2010

Redacted version of MFC Final Storage Notice (Admin Doc 13) by D. Hannemann on 29 Sept 2010

Redacted version of MFC IVF Lab Report (Admin Doc 14) by D. Hannemann on 29 Sept 2010

Administrative Attachments:
Document 1: (DOC - 01/12/2010) Response letter from V. Galat on providing informed consent documents
Document 2: (PDF - 01/24/2010) questions to V. Galat from NIH
Document 3: (DOC - 01/24/2010) IIB analysis by NIH staff
Document 4: (PDF - 02/17/2010) questions to CMRC from WG
Document 5: (PDF - 04/02/2010) April 2 2010 email from Galat
Document 6: (DOC - 04/02/2010) April 2 2010 email attachment from Galat
Document 7: (PDF - 07/12/2010) NIH Email Questions to Submitter on July 8 2010
Document 8: (PDF - 07/12/2010) Submitter Email Response on July 9 2010
Document 9: (PDF - 07/12/2010) IRB Exemption Letter
Document 10: (PDF - 07/12/2010) [redacted] Statement on Embryo Transfer
Document 11: (PDF - 07/15/2010) 15 July Email Response from Submitter
Document 12: (PDF - 07/28/2010) 27 July Email Response from Submitter

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Document 13: (PDF - 09/29/2010) Frozen Embryo Donation Consents_redacted
Document 14: (PDF - 09/29/2010) Fresh Embryo Donation Consents_redacted
Document 15: (DOC - 07/28/2010) ESC Consent
Document 16: (PDF - 07/28/2010) 28 July 2010 Email from Submitter
Document 17: (PDF - 07/28/2010) IVF Clinic Attestation
Document 18: (PDF - 10/20/2010) Galat response #1 19 Oct 2010
Document 19: (PDF - 10/20/2010) Galat response #2 19 Oct 2010
Document 20: (PDF - 10/26/2010) Galat response 25 October 2010

Status History:
Draft: 09/24/2009
Pending: 11/18/2009

Emails Sent: 11/18/2009-New_Applicaton_Email

Added By: Commons\vgalat **On:** 09/24/2009 | **Last Updated By:** NIH\gadboisel **On:** 10/26/2010 | **Record ID:** 7

Total Record Count = 1 *

Administration Page

Report - NIH Form 2890 Admin Site

(7)

Children's Memorial Research Center

Office of Sponsored Programs

2300 Children's Plaza, Box 205
Chicago, Illinois 60614-3394
773.755.6302
Fax 773.755.6533
www.childrensmrc.org

Affiliated with
Northwestern University's
Feinberg School of Medicine

Date: 11/10/2009

NIH Stem Cell Registry:

I hereby certify that the statements in the Request for Human Embryonic Stem Cell Line to be Approved for Use in NIH Funded Research (NIH Form 2890), submitted by *Dr. Vasil Galat, PhD* below, are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties (U.S. Code, Title 18, Section1001).

I further confirm that that I have the authority and/or rights pertaining to the human embryonic stem cell line(s) identified in item 6 of the form to make this request for NIH review and determination of eligibility for use in NIH funded research (e.g., I am the owner, deriver or licensee or have written permission of the same to submit). Any and all restrictions on the use of the stem cell line are clearly and completely identified in item 8 of the form.

Assurance Statements (mark the appropriate statement with an "X"; you may only check **one** Assurance statement.):

_____ Assurance in accord with Section II(A) of the NIH Guidelines:

I hereby assure that the donation of the embryo from which the cell line(s) identified in item 6 was derived was in accordance with the elements of Section II(A) of the NIH Guidelines on Human Stem Cell Research.

OR

___x__ Assurance in accord with Section II(B) of the NIH Guidelines:

I hereby assure that the embryo from which the cell line(s) identified in item 6 of the form was derived was donated prior to July 7, 2009, and the embryo: 1) was created using in vitro fertilization for reproductive purposes and was no longer needed for this purpose; and 2) was donated by individuals who sought reproductive treatment ("donor(s)") who gave voluntary written consent for the human embryo to be used for research purposes. The applicant is advised that the Working Group of the Advisory Committee to the NIH Director will consider submitted materials taking into account the principles articulated in Section II(A) of the NIH Guidelines for Human for Human Stem Cell Research, 45 CFR 46 Subpart A, and the following points to consider: during the informed consent process, including written and oral communications, whether the donor(s) were: (1) informed of

other available options pertaining to the use of the embryo ; (2) offered any inducements for the donation of the embryo ; and (3) informed about what would happen to the embryo after the donation for research.

OR

_____ **Assurance in accord with Section II(C) of the NIH Guidelines:**

I hereby assure that the embryo from which the cell line(s) identified in item 6 of the form was derived was donated outside the United States on or after July 7, 2009, and the alternative procedural standards of the foreign country where the embryo was donated provide protections at least equivalent to those provided by Section II(A) of the NIH Guidelines on Human Stem Cell Research.

I acknowledge that I have read, understood, and agreed to the information provided on the form, including the Instructions for completing the form, and the Certification, Authority and Assurance provided above.

Harmony Maple, MPA
Director, Office of Sponsored Programs
Children's Memorial Hospital
2300 Children's Plaza, No. 205
Chicago, IL 60614
773-755-6334 Phone
hmaple@childrensmemorial.org

(9)

Children's Memorial Research Center

Office of Research
Integrity and Compliance

2300 Children's Plaza, Box 205
Chicago, Illinois 60614-3394
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Fax 773.755.6304
www.childrensmrc.org

Affiliated with Northwestern University's Feinberg School of Medicine

January 17, 2007

Vasil Galat, PhD
CMRC/Developmental Systems Biology, Box#204

Re: **Establishment of Embryonic Stem Cells Bank, IRB#2007-13057**

Dear Dr. Galat:

The Institutional Review Board reviewed the above-named study and has determined that it is exempt from IRB review.

This determination was based on 45 CFR 46.101(b)(4): "Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects."

Any proposed changes to this research must be submitted to the IRB, prior to implementation, in order to determine if the research still qualifies for exempt status. If the IRB finds that the research is no longer eligible for exemption, you will be notified whether the study needs to be submitted for either expedited or full board review.

The above IRB number has been assigned to this study for tracking purposes only.

Sincerely,

Ellen R. Brooks, PhD, Chair
Institutional Review Board
Children's Memorial Research Center

(10)

NORTHWESTERN UNIVERSITY COMMITTEE ON HUMAN STEM CELL RESEARCH

Chair of NUCHSCR Lewis J. Smith, MD
Associate VP for Research
750 N. Lake Shore Drive, Suite 700
Chicago, IL 60611

l-smith@northwestern.edu
Phone: (312) 503-2615

NORTHWESTERN UNIVERSITY

August 2, 2007

Vasil Galat, PhD, HCLD
Children's Memorial Research Center
2300 Children's Plaza, Box 204
Chicago IL, 60614

Project Number: NU ESC0002
Project Title: Establishment of Embryonic Stem Cell Bank
Review Date: 04/18/2007
Status: Approved on 07/27/2007

The Northwestern University Committee on Human Stem Cell Research (NUCHSCR) has now granted approval for the above referenced project. This approval is granted with the understanding that the investigator will (if applicable):

- If using non-NIH approved human embryonic stem cell lines, you must work with your sponsored project's office to ensure you do not violate federal regulations.
- Do not change the procedures or scope of the research without prior NUCHSCR approval of those changes.
- Promptly report any unanticipated problems involving risk.
- As this project falls under categories B1 & B2, provide the committee with a follow-up report one year after initial approval has been granted. In the report describe any new findings which may have made your research redundant, provide a rationale for the continuation of the research, and indicate any new ethical problems that might arise based on your research findings from the past year.

Sincerely,

Lewis J. Smith, MD
Chair, NUCHSCR

(11)

Children's Memorial Research Center

2300 Children's Plaza, Box 204
Chicago, IL 60614
773-755-6598
773-733-6385 Fax
v-galat@northwestern.edu
http://www.childrensmrc.org/stemcellcore

Vasili Galat, Ph.D. HCLD.

Director, CMRC iPS and Human Stem Cell Core Facility,
Research Assistant Professor
Northwestern University
Feinberg School of Medicine

November 9, 2009

Eleven CMRC (CM) hESC lines were derived from embryos donated in US prior July 7, 2009 are being submitted as one submission for review by ACD for approval for addition to NIH Stem Cell Registry. The project titled Development of Human Embryonic Stem Cell Bank was supported by the Illinois Regenerative Medicine Institute (IRMI) State of Illinois funding. The IRB CMRC has determined that the protocol is exempt (attachment 2). The study was further reviewed and approved by ESCRO Committee NUCHSCR (attachment 3). Nearly 300 embryos donated for research purposes from reproductive cycles between years 1998 -2009 were shipped to CMRC from IVF centers. Major contributors of donated embryos were [redacted] and Midwest Fertility Center, IL (see Acknowledgment letters from [redacted] and MFC, attachment 4). Patient consented embryos for research were consulted on research activity with the embryos and were not offered any inducement for the donation. They had other options at the time of donation i. e. to discard the embryos or donate it to other couples (see Sample Consents: [redacted] Disposition for Frozen Embryo(s) Form, [redacted] Confirmation Form, MFC Informed Consent for Embryo Transfer, MFC Embryo Storage Final Notice, attachment 5). All embryos were sent to CMRC with no identifiers. Signing Official Approval Letter (attachment 6).

Vasil Galat, Ph.D., HCLD

Galat

Amos E. Madones, M.D.
Donna E. Pratt, M.D.

(12)

MFC
MIDWEST FERTILITY CENTER

4333 Main Street
Downers Grove, IL
60515

T: 630.810.0212
F: 630.810.1027
1.800.244.0212

Internet:
www.ivf.us

E-mail:
fertility@ivf.us

Offices:
Downers Grove, IL
Naperville, IL
Chicago, IL
Merrillville, IN
Munster, IN
Valparaiso, IN

October 28th, 2009

To Whom it May Concern

Midwest Fertility Center collaborates with CMRC iPS and Human Stem Cell Core Facility at Children's Memorial Research Center (CMRC) for the establishment a library of human embryonic stem cell lines, approved by the Children's Memorial Hospital IRB (IRB #2007-13057). The left over embryos donated for research purposes from reproductive cycles between years 1998 -2009 were transferred to CMRC along with the Sample Consent Form disclosing that patients had the option to discard the embryos or donate them for research. The shipments include de-identified vials of frozen embryos (six patients) and de-identified fresh embryos (nine patients). The following collaborative studies resulted from this work:

Galat V., Ozen S., Greiss H., Hendrix M., Iannaccone P. The advantage of microsurgical techniques for human embryonic stem cell derivation, established on embryos donated after pre-implantation screening (PGD). Fertility Sterility. 2008. V. 90 P. S249.

Galat V., Greiss H., Iannaccone P., Hendrix M. A microsurgical approach developed for hESC derivation in animal-free conditions from embryos sampled by single cell biopsy. Proceeding of ISSCR meeting. 2008. P. 177.

ART Lab Director of MFC

Hisham F. Greiss MD, PhD, HCLD.

(13)

From:	Vasil Galat
To:	HESCREGISTRY (NIH/OD)
Cc:	HMaple@childrensmemorial.org; Philip Iannaccone; Colleen Grogan
Subject:	Re: New hESC Registry Application Request #2009-ACD-009 MFC consents
Date:	Tuesday, July 27, 2010 2:27:35 PM
Attachments:	MFC frozen Consents .pdf MFCfresh Consents.pdf ESCconcent2009.doc ATT00001..txt

Dear Dr. Gadbois,

I have supporting documentation for the lines established from embryos donated by MFC. The line CM7 was established in May 2008 from thawed de-identified embryos. All six consents of the patients donated frozen embryos (from 1996, 1998, 2001, 2004, 2005), with a statement "donate for research" are presented (see "MFC frozen consents"). CM7

The supporting documentation for the fresh embryos donated after PGD screening was requested only for the donations from which hESC lines were developed (see "MFC fresh consents"). The line CM6 was established in May 2008 from a donation verbally consented for research as stated (with a signature of IVF director) in a copy of patient chart. CM6 The line CM2 was established from embryos donated 9/1/07 consented by the patient " Donate to Northwestern for research". Please note that "donate to research" option is made in handwriting reflecting that this option was added after establishing collaboration between CMRC and MFC and the leftover embryos were discarded earlier. The consent form was modified at a later time (as seen from the sample consent from 2008 provided with the submission) allowing "donation for research" as a standard option. Additionally, "donate to Northwestern" reflects that patients were provided the information about specifics of hESC research in CMRC, NU. I am also attaching the sample consent offered by us for embryo donation ("Consent 2009") in which we incorporated the novel ethical requirements spelled out in the NIH guidelines. Please let us know if you consider this form adequate for submission of the hESC lines for prospective registration with Administrative review. I expect to receive MFC IVF lab director statement and forward it to you tomorrow. CM2

In support of this application I must say that MFC lines CM6 and CM7 contributed to several studies and possess a unique ethnical background according to the study: L. C. Laurent, C. M. Nievergelt, C. Lynch, E. Fakunle, J. Harness, U. Schmidt, V. Galat, A. L. Laslett, T. Otonkoski, H. Keirstead, A. Schork, H-S. Park, J. F. Loring. Restricted Ethnic Diversity in Human Embryonic Stem Cells. Nature Methods. 2010. 1 (7). 6-7

Sincerely,

V. Galat

(14)

Amos E. Madanes, M.D.
Donna R. Pratt, M.D.

MFC
MIDWEST FERTILITY CENTER

4333 Main Street
Downers Grove, IL
60515
T: 630.810.0212
F: 630.810.1027
1.800.244.0212

Internet:
www.ivf.us

E-mail:
fertility@ivf.us

Offices:
Downers Grove, IL
Naperville, IL
Chicago, IL
Merrillville, IN
Munster, IN
Valparaiso, IN

July 26, 2010

The embryos consented for research on 9/01/07 and 5/04/07 were from the patients undergoing PGD screening. The donated to CMRC embryos were not considered for the embryo transfer or freezing for different reasons i.e. those with abnormal, inconclusive results or no results (nuclei were not present in the testing sample). I personally consult couples, including those who are planning a PGD screening, prior (typically 45 days before) beginning of IVF cycle. For those couples expressed the interest in donating embryos I explain the nature of prospective research, specifically, the usage of donated embryos for hESC research. During embryo transfer on day 5 the embryologist confirms the fate of the remaining embryos. The patients donated their embryos on 5/04/07 finalized their decision and notified me after the embryo transfer at which I made a correspondent statement in the patient chart. The patients were given ample time to change their mind and they can withdraw the consent up to day 6 of embryo development, the day when donated embryos were transferred to CMRC.

Do not hesitate to contact me for further clarifications.

Hisham Greiss, MD, PhD, HCLD

Cell Line "CM2"
(NIH Notation)

15

MFC Midwest Fertility Center

Date: 9/1/07

Informed Consent for Embryo Transfer and Embryo Cryopreservation

We, [redacted] (wife)

and [redacted] (husband) agree to the transfer of 2 embryos on 1-1-07 (today's date). We have read and signed a separate consent detailing the risks of multiple births and agree again that we are accepting these risks. We are willingly and Knowingly consenting to the transfer of these embryos.

We also understand and consent to the following:

- ☐ We do not have any embryos remaining for freezing
- ☐ We want all of the remaining embryos discarded
- ☐ We want those of the remaining embryos suitable for cryopreservation frozen and those not suitable for cryopreservation discarded.
- ☒ Donate to Northwestern for research

[redacted]
9-1-07
Date

[redacted]
Wife, Print Name

[redacted]
9-1-07
Date

Signature of Husband

[redacted]
Husband, Print Name

[redacted]
9/1/07

Signature of Witness

[redacted]
Witness, Print Name

8/2002

Cell Line "CML" (NIH notation) (16)

cell B

[redacted] Allergies: NKDA ☑ IVF ☐ ICSI ☑ AZH ☐ FET ☐ EGG DONOR ☐ RECEIPENT ☑ CRYO

Site: | rance/Billing Signature: [redacted] | Date: 4/08

IVF History	(cancelled)	(completed)
MFC		
Other		

Consents signed: ☑ IVF ☐ ICSI ☑ AZH ☐ FET ☐ EGG DONOR ☐ RECEIPENT ☑ CRYO

SART ☐ NO Last Pap PGD 2 # Of Embryos to be transferred [redacted]

Log #: FA-1458

THE MIDWEST FERTILITY CENTER – IVF / FET CYCLE

Embryo Glue ☑ Yes ☐ No FSH-

Name: [redacted] Diagnosis: [redacted] Cycle#: 1

Spouse / Partner: [redacted]

ENDO	RIGHT (follicles)	LEFT (follicles)	LUP	M	B	CYCLE	DATE 2008	P4	E2	COMMENT
6.5	4 (BASELINE)	6 (BASELINE)	0.1			E		1	39	US,E2,P4
				1/1	1/2	1	4/19			
				1/1	1/2	2	20			
6.5	8	15		1/1	1/2	3	21	1.4	197	US,E2,P4
				1/1	1/2	4	22			
7.5	X X X X X X	X X X X X	V	1/1	1/2	5	23	1.5	525	US,E2,P4
				1/1	1/2	6	24			
12ml	X X X X X X X X	X X X X X		1/1	1/2	7	25	1.6	1376	US,E2,P4
12m	X X X X X X X X X	X X X X X X X		1/1	1/2	8	26		1891	US,E2,P4
				1/	1/ X	9	27			
						10	28			
					10cc (HCG)	11	29			Ret 7:30
						12	30			
						13	5/1			
						14	2			
						15	3			
						16	4			
						17	5			
						18	6			
						19	7			
						20	8			
						21	9			
						22	10			
						23	11			
						24	12			
						25	13			

Note: * very hard to visualize follicles, cyst behind

Day 0 Oocytes	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Egg Stage V-15																				
D_1 Fert N-15	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2					
D_3 Cells N-15	8	8	8	8	8	8	8	8	M	8	8	8	8	8	8					
D_3 Symetry	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S					
D_3 Frag (%)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0					
D_3 Overall Grade	G	G	G	G	G	G	G	G	G	G	[illegible]	F	G	G	G					
D_3 Fate C/D/T												vacuole								

Abnormal nuclei

* no embryos Donated for research. Patient consent verbally.

Day 5/6 Morphology	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Day 5/6 Morphology		Bl				EB						EB		8C	
Inner cell mass		G				G						G			
Trophoblast		F				G						G			
Blastocyst Overall Grade		F				G						G			
D 5/6 Fate F/D/T		F				T						T		D	

G Fert 50167 5/4/08
G I 501319
G II 501326
G Oocyte
G Mops 5T511
G Freeze
G Thaw
Ovoil 20,374

Initials: RET. INSEM ICSI VERT AZH PGD CRYO THAW ET

Comments: * On [illegible] * 1 Bl, 1 8C IVF3, 2W

1st Beta	N	P
#Sacs		
#FHT		
#Live Birth		

Revised 10/2007

Cell Line "CM7" (WITH notation).

(17)

MFC
MIDWEST FERTILITY CENTER

4333 Main Street
Downers Grove, IL
60515
T: 630.810.0212
F: 630.810.1027
1.800.244.0212

Internet:
www.fcus

E-mail:
[redacted]fcus

Offices:
Downers Grove, IL
Naperville, IL
Chicago, IL
Elk Grove Village, IL
Palos Heights, IL
Merrillville, IN
Munster, IN
Valparaiso, IN

Aimee E. Maslanka, M.D.
Donna E. Pratt, M.D.
Natalie Schultz, M.D.

1/1/06

Embryo Storage Notice
Lab Log# _____ [redacted]188

Dear [redacted]:

Midwest Fertility Center is currently storing your embryos which were frozen on 4/17/96. **A payment of $500.00 is required each calendar year to continue your embryo storage. Please check the appropriate box, sign and return the form with your payment within 30 days of receipt of this letter. Failure to remit payment for annual storage will constitute your consent to discard your embryos. If you have any questions concerning this matter, please call Midwest Fertility Center (630-810-0212).**

[ ] **Continue to store our frozen embryos. Enclosed is payment for 2006**

[ ] **Discard our frozen embryos**

[X] **Other (address change, etc.)** Please donate for research

Your signature [redacted] **Date:** 2-23-06
Partner's signature [redacted] **Date:** 03-17-06

Your current address
[redacted]0

Address for remitting payment and future communication

Midwest Fertility Center
4333 Main Street
Downers Grove, IL 60515
Tel: 630-810-0212 Fax: 630-810-1027

Call Line "CM7" (With notation) (18)

MFC
MIDWEST FERTILITY CENTER

4333 Main Street
Downers Grove, IL
60515
T: 630.810.0212
F: 630.810.1027
1.800.244.8212

Internet:
www.ivf.us

E-mail:
fertili .us

Offices:
Downers Grove, IL
Naperville, IL
Chicago, IL
Elk Grove Village, IL
Palos Heights, IL
Merrillville, IN
Munster, IN
Valparaiso, IN

9/22/03

2/23/06

Embryo Storage Final Notice
Lab Log# [redacted]

[redacted]

Dear [redacted]:

Midwest Fertility Center is currently storing your embryos which were frozen on 11/19/04. **A payment of $500.00 is required each calendar year to continue your embryo storage. Please check the appropriate box, sign and return the form with your payment.**

Please remit payment within 10 days of receipt of this letter. This is your final notice as other notice attempts were not acknowledged.

Failure to remit payment for annual storage will constitute your consent to discard your embryos as stated in the Consent for Cryopreservation of Human Embryos that you have previously signed. If you have any questions concerning this matter, please call Midwest Fertility Center (630-810-0212).

[ ] Continue to store our frozen embryos. Enclosed is payment for 2006

[ ] Discard our frozen embryos

[✓] Use my frozen embryos for research purposes

[ ] Other (address change, etc.) _____

Your signature [redacted] **Date:** 2/24/06
Partner's signature [redacted] **Date:** 2/24/06

Your current address _____

_____

Telephone Number _____

Address for remitting payment and future communication
Midwest Fertility Center
4333 Main Street
Downers Grove, IL 60515
Tel: 630-810-0212 Fax: 630-810-1027

Cell Line "CM7" (WITH notation)

(19)

MIDWEST FERTILITY CENTER

4333 Main Street
Downers Grove, IL
60515
T: 630.810.0212
F: 630.810.1027
1.800.244.0213

Downers Grove, IL
Naperville, IL
Chicago, IL
Elk Grove Village, IL
Palos Heights, IL
Merrillville, IN
Munster, IN
Johnston, IN

3/15/...

[redacted]

Embryo Storage Final Notice
Lab Log# _____

Dear [redacted]:

Midwest Fertility Center is currently storing your embryos which were froze
4/12/05. A payment of $500.00 is required each calendar year
continue your embryo storage. Please check the appropriate box, sign and ret
the form with your payment.

**Please remit payment within 10 days of receipt of this letter. This is you
final notice as other notice attempts were not acknowledged.**

Failure to remit payment for annual storage will constitute your consent to discard
your embryos as stated in the Consent for Cryopreservation of Human Embryos
that you have previously signed. If you have any questions concerning this
matter, please call Midwest Fertility Center (630-810-0212).

[ ] Continue to store our frozen embryos. Enclosed is payment for 2006

[ ] Discard our frozen embryos

[X] Use my frozen embryos for research purposes

[ ] Other (address change, etc.)

Your signature _____ Date: _____
Partner's signature _____ Date: 03/23/04

Your current address

[redacted]

Address for remitting payment and future communication
Midwest Fertility Center
4333 Main Street
Downers Grove, IL 60515
Tel: 630-810-0212 Fax: 630-810-1027

Cell Line "CM7" (with notation)

MIDWEST FERTILITY CENTER

3/15/06 [redacted] 03 Embryos (20)

Embryo Storage Final Notice
Lab Log# _____

Dear [redacted]

Midwest Fertility Center is currently storing your embryos which were frozen on 6/13/05 & 6/12/03. A payment of $500.00 is required each calendar year to continue your embryo storage. Please check the appropriate box, sign and return the form with your payment.

Please remit payment within 10 days of receipt of this letter. This is your final notice as other notice attempts were not acknowledged.

Failure to remit payment for annual storage will constitute your consent to discard your embryos as stated in the Consent for Cryopreservation of Human Embryos that you have previously signed. If you have any questions concerning this matter, please call Midwest Fertility Center (630-810-0212).

[ ] Continue to store our frozen embryos. Enclosed is payment for 2006

[ ] Discard our frozen embryos

[X] Use my frozen embryos for research purposes

[ ] Other (address change, etc.) _____

Your signature [redacted] Date: 3/24/06
Partner's signature [redacted] Date: 03/29/06

Your current address [redacted]

Address for remitting payment and future communication
Midwest Fertility Center
4333 Main Street
Downers Grove, IL 60515
Tel: 630-810-0212 Fax: 630-810-1027

Cell Line "CM7" (WITH notation)

(21)

MIDWEST FERTILITY CENTER

4333 Main Street
Downers Grove, IL
60515

T: 630.810.0212
F: 630.810.1027
1.800.244.0212

Internet:
www.ivf.us

E
lity@ivf.us

Offices:
Downers Grove, IL
Naperville, IL
Chicago, IL
Elk Grove Village, IL
Palos Heights, IL
Merrillville, IN
Munster, IN
Valparaiso, IN

Amos E. Maloney, M.D.
Donna E. Pratt, M.D.
Natalie Schultz, M.D.

January 23, 2007

[redacted]

Embryo Storage Final Notice

Dear [redacted]

Midwest Fertility Center is currently storing your embryos which were frozen on 3/22/01. A payment of $500.00 is required each calendar year to continue your embryo storage. Please check the appropriate box, sign and return the form with your payment.

Please remit payment within 10 days of receipt of this letter. This is your final notice as other notice attempts were not acknowledged and verification of delivery was received. Your account will be sent to a collection agency in the amount of $3,000.00 unless payment or this notice is returned with the order for discard or research.

Please check your response and let us know your wishes – we need your answer:

[ ] **Continue to store our frozen embryos. Enclosed is payment for 2007.**

[ ] **Discard our frozen embryos**

[✓] **Use my frozen embryos for research purposes**

[ ] **Other (address change, etc.)**

Your signature [redacted] **Date:** 1/24/07
Partner's signature [redacted] **Date:** 1-24-07

Your current address [redacted]

Telephone Number [redacted]

Address for remitting payment and future communication
Midwest Fertility Center
4333 Main Street
Downers Grove, IL 60515
Tel: 630-810-0212 Fax: 630-810-1027

In the past several times (6) I have received letters and stated if we did not respond they would be discarded. I am not sure why this did not take place!

Cell Line "CM7" (WIH notation)

MIDWEST FERTILITY CENTER

4333 Main Street
Downers Grove, IL
60515
T: 630.810.0212
F: 630.810.1027
1.800.244.0212

Internet:
www.ivf.us

E-mail:
( )f.us

Offices:
Downers Grove, IL
Naperville, IL
Chicago, IL
Elk Grove Village, IL
Palos Heights, IL
Merrillville, IN
Munster, IN
Valparaiso, IN

Amos E. Madanes, M.D.
Donna E. Prum, M.D.
Natalie Schultz, M.D.

22

2/7/2006

[redacted]

Embryo Storage Final Notice

Dear [redacted]

3/6/98

The Midwest Fertility Center, Ltd., is currently storing your embryos which were frozen on 3/6/98. A payment of $500.00 is required each calendar year to continue your embryo storage. Please check the appropriate box and complete/return the lower portion of this letter.

Please remit payment within 10 days of receipt of this letter. This is your final notice as other notice attempts were not acknowledged.

The Midwest Fertility Center, Ltd.
4333 Main Street
Downers Grove, IL 60515

- ☐ **Please continue to store our frozen embryos. Enclosed is my payment of $500.00 for the year 2006.**
- ☐ **Please discard my frozen embryo samples.**
- ☒ **Please use my frozen embryos for research purposes.**

Note: Failure to remit payment for annual storage will constitute your consent to discard embryos as stated in the Consent for Cryopreservation of Human Embryos that you have previously signed.

[redacted]

Patient Signature

[redacted]

Patient's Spouse/Partner's Signature

[redacted]

Permanent Street Address

[redacted]

City, State, Zip Code

Area Code – Telephone Number

2/22/06

Date Signed

If you have any questions concerning this matter, please call
Midwest Fertility Center

(23)

Email attachment from submitter

January 10, 2010

Thank you for reviewing our submission. All submitted CM lines are established prior to July 7, 2009. We were following the Instructions for Completing NIH Form 2890 for Working Group ACD review for embryos donated in US prior to July 7, 2009 Section II(B) http://hescregapp.od.nih.gov/NIH_Form_2890_Instructions.htm
Considering the questions addressed to us by the ACD Working Group we suppose that we might have overlooked some document(s) with additional requirements for the submission hESC lines for registration.

It may not be possible for us to provide the copies of informed consent for a particular embryo due to the absolute requirement for de-identification imposed by our IRB. Further, our information is provided in accordance with confidentiality requirements of the partner Reproductive Centers. Because of those requirements we do not have the actual consents of the patients. IVF lab directors responded that they were not comfortable to forward it to us. The consents provided with the submission are "Sample" as stated in the Summary. They may belong to the patients whose embryos are actually shipped to CMRC from the IVF centers under the terms of our IRB approvals. The Sample consents serve to demonstrate the existing IVF policies regarded to all patients and confirm that embryos were generated for reproductive purposes while the patients had other choices, e.g. to discard the embryos. To our knowledge the IVF centers that contributed the embryos to CMRC never generated the embryos solely for research purposes. We contend that the "research category" in the context of hESCs is relevant for producing of parthenogenetic or somatic cell nuclear transfer "cloned" hESC lines, which involves using donated oocytes (eggs). The CM lines did not originate from oocytes, rather they were established from residual embryos generated for reproductive purposes.

We did not specify the type of embryos used e.g. from frozen, PGD or fresh cycle because there are no differences in terms of supporting documentation: given the de-identification requirement it is not possible for us to establish which procedure was used in a given case from the clinic. Additionally, we wanted to submit the lines in one submission, which according to the guidelines requires the same information for each line.

(24)

With respect to our arrangements with the IVF centers, V. Galat was an off-site director of the IVF program at [redacted]. There was a need to separate cryostored embryos intended for reproduction from embryos donated for research. [redacted] was not able to utilize those embryos donated for research or to conduct research by itself. They were, however, obligated to donate the embryos when meaningful research is possible (as stated in the Sample Confirmation form). V. Galat advocated for transfer of the embryos donated for research to CMRC. It took about a year to generate [redacted] and CMRC IRB permissions for embryo transfers to CMRC. By the time of actual embryo transfer V. Galat was no longer a part of [redacted] IVF program and the shipment was arranged by the new director. Only frozen de-identified embryos were transferred from [redacted] to CMRC.

Not part of 12/9/10 review.

Additionally, V Galat advocated the idea of developing new lines of hESC at reproductive meetings such as ASRM and CARE and encouraging the centers to transfer donated embryos for research to CMRC instead of discarding them. This resulted in establishing a relationship with the Midwest Fertility Center (MFC) that provided de-indentified frozen and fresh embryos.

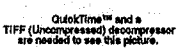
As to when informed consent took place: this was done several times, upon patient enrolment into the reproductive cycle, during the embryo transfer and before the embryo disposition. The patients discuss their choices each time with a counselor. Particularly at [redacted], as seen from Sample consents for frozen embryos, patients had the following choices: to continue storage, to discard embryos, to donate embryos for scientific research or to attempt to donate to another infertile couple. It was also clearly stated that patients may refuse and their future treatment would not be affected. Further, patients were told that they would no longer have access to their specimens once donated.

In MFC at the time of embryo transfer (see Sample Consent) patients were presented with the options to freeze the remaining embryos, to discard them or donate them for research. At the time of embryo disposition patients were again asked whether they wanted to continue to store embryos, donate them for research or discard them. In 2007 CMRC developed a new consent form addressing embryo donation specifically for stem cell research and forwarded it to MFC but it was not in place at the time of the donation

to CMRC. Nevertheless, the IVF director was verbally explaining to the patients that embryos would be directed for stem cell research.

The approved IRB application has not been changed since 2007 because the exempt status of the study did not change and IRB has not requested changes. We are going to publish our protocols and results and have a manuscript in preparation at this time. We will be happy to share these procedures when they are publicly disclosed. We would be happy to provide them to you at this time with appropriate non-disclosure arrangements. Genebank and GEO submissions for example are held confidential until the papers are published and the authors release the data. There does not seem to be such a safeguard in the stem cell registry.

Thank you for your consideration.



Vasil Galat, Ph. D.

(26)

Email attachment from submitter

April 2, 2010

Dear Dr. Gadbois,

We have sent the questions of the Committee to the IVF centers and waiting for their reply. I have the notion that they are going to provide input but it is not easy to establish the exact timeframe for their response because they are not motivated to go these extra miles. Besides, they are confused about to what exactly they have to attest. Let me go over your questions to make sure we are gathering ample and appropriate information.

Questions: Could you please provide:

1. Specific dates of embryo donation and hESC derivation for each hESC line.

We will provide the timing of fresh embryo donation and hESC lines establishment. There is no possibility for us or for the IVF centers to provide a date of embryo donation of frozen embryos because they were de-identified. Nether of us knows exactly which embryos were in the particular straws we used to establish the lines. Do you think the situation with frozen embryos is properly explained and will be accepted by the Committee? This de-identification was required by our IRB in order to do the work and was imposed prior to the establishment of national guidelines.

2. *A copy of the research protocols, redacted if necessary, with information on whether fresh embryos were used, whether the embryos were poor quality, leftover from PGD, and/or clinical grade embryos, and what procedures were used for identifying those embryos and shipping them to CMRC.*

I need some clarification on this one. The hESCs manipulations and handling were done accordingly with the recommendations of the Thomson group following the WiCell protocols handed to us at their workshop. Would you like us to submit these protocols? The hESC derivation was done differently, with optimization for xeno-free conditions, specifically, ICM from blastocysts were isolated not by immunosurgery but mechanically (microsurgically). In some cases a human feeder cells instead of mouse were used to support hESCs grows. Shall we submit the protocols for microsurgical ICM isolation and human feeder cell preparation?

We requested the information from Midwest Fertility Center, which provided the fresh

embryos and embryo procedures that were used, etc. We would not be able to recover any history about the frozen embryos for the reason mentioned above. ~~The shipment of de-identified frozen embryos was done in a dry shipper from [redacted]~~. Shall I submit a FedEx requisition copy? The delivery of de-identified frozen embryos from Midwest Fertility Center (Chicago area) was done in a dry shipper by the embryologist. I used a portable transporter to pick up de-identified fresh embryos from Midwest Fertility Center.

Not part of 12/9/10 presentation.

3. *If fresh (non-frozen) embryos were donated, please provide information about the timeframe allowed families to make decisions about consent and donation.*

In my former letter to the Committee I wrote: "As to when informed consent took place: this was done several times, upon patient enrolment into the reproductive cycle, during the embryo transfer and before the embryo disposition. The patients discuss their choices each time with a counselor". Additionally, I can say that in every IVF center, (including ones donating embryos to CMRC) the patients discuss the possible outcome of treatment and are offered options to handle the spare embryos upon enrolment in reproductive cycle, which happened roughly one to three month prior to oocyte retrieval. At the day of oocyte retrieval the patient is informed of how many eggs were collected, at which point the patients can make a rough estimate of whether they will have residual embryos. Usually one to three embryos, depending on their quality and the age of the patient, are transferred back. Upon fertilization, the day after oocyte retrieval, the patient is informed of how many eggs are fertilized, which provides the patient with a more precise idea about the chance of having residual embryos. At the day of embryo transfer (usually day 3 or day 5) the patient knows precisely how many embryos were properly developed and makes a final decision. Typically patients choose to freeze extra embryos until the outcome of treatment is known. Thus, the families have ample time to make decisions about consent and donation and can reverse their decision at any point. Do you feel I fully addressed your question or the statements from IVF directors are still needed?

4. Documentation that for each hESC line, the embryo donor gave written informed consent (rather than just the sample consents already provided). This could be accomplished in any of the following ways:
Could the IVF clinics attempt to track back to the embryo donor for each hESC line in

order to provide redacted consent forms?

If de-identification precludes the submission of an actual, redacted consent form linked to the donor of each hESC line, could you attempt to track back to the time window around the embryo donation and verify that all IVF patients who donated embryos to gave consent for hESC research, using a form that has been provided to the WG? For example, if line X came from clinic Y, the IVF clinic director at clinic Y could review files of all embryo donors to CMRC at that time. The IVF clinic director should attest that he or she reviewed all files and verified that consent for hESC research was given.

Again, tracking back particular patients for IVF centers is attainable only for freshly donated embryos from MFC. For the frozen embryos it would not be possible to tell which consent form belongs to which hESC line because de-indentified straws were shipped in bulk. Seemingly the statements from the IVF clinic that files of all donors are verified to show that consent for hESC research was given is the only answer.

I would like to draw to your attention that donation of embryos from [redacted] was done in coordination with [redacted] University IRB. IRB review of embryo donation to CMRC was solicited by [redacted] M.D. a medical director of In Vitro Fertilization laboratory Division of Reproductive Endocrinology of [redacted] of [redacted]. The IRB reviewed the adherence of embryo donation to the ethical requirements and guidelines. The verification of consents was done at that time and embryos donated for research were pulled to a specific location in cryostorage. De-identification of the straws was performed in the presence of witnesses, which confirmed the label of the straw matched the patient donated embryos for research before it was removed. You can find a confirmation that consent forms were reviewed in the letter provided with the submission. Here is from the letter of the [redacted] IRB Chair [redacted] M.D. :

Not part of 12/9/10 presentation.

" Dear Dr. [redacted],

I have reviewed your May 5, 2007 request to donate residual embryos to the CMRC for stem cell research purposes. Your division has obtained consents to use these residual embryos in research. The embryos will be sent with no identifiers. There will be no financial compensation of any type for this donation...".

~~The letter from [redacted] IRB is provided with the submission, file name "IVF_Letters". Do you regard this document as a confirmation that consent forms were actually verified or you would need another statement from IVF director on this matter?~~

Not part of 12/9/10 presentation.

Regarding the MFC embryos, there is a statement from IVF lab director saying that: "...The left over embryos **donated for research purposes** from reproductive cycles between 1998-2009 were transferred to CMRC along with the Sample Consent Form disclosing that patients had the option to discard the embryos or donate them for research..."

The letter from MFC IVF lab director H. F. Greiss M.D., PhD, HCLD is provided with the submission, file name "IVF_Letters". Do you regard this document as a confirmation that consent forms were verified or you would need additional statement from IVF director addressing this point?

5. Documentation of whether donors were given more specific information (including in oral form) about the nature of the hESC research. This could be documented in attestations from IVF clinic medical directors.

We do not have such documentation for the frozen embryos. The majority of these donations was done before the human embryonic stem cells were even described. The donors consented the embryos "for research" rather then "stem cell research". Regarding the fresh embryos from MFC in my previous letter I wrote:

"CMRC developed a new consent form addressing embryo donation specifically for stem cell research and forwarded it to MFC but it was not in place at the time of the donation to CMRC. Nevertheless, the IVF director was verbally explaining to the patients that embryos would be directed for stem cell research".

If I have had consents specifically addressing hESC research, I would submit my application directly to Administrative review. I felt encouraged in submitting our lines to ACD review because there were, basically, two ultimate requirements in the Instruction for Completing NIH Form 2890:

Under Section II(B) of the NIH Guidelines, the supporting documentation must demonstrate that the hESCs were derived from human embryos:

1. that were created using in vitro fertilization for reproductive purposes and were no longer needed for this purpose; and
2. that were donated by donor(s) who gave voluntary written consent for the human embryos to be used for research purposes.

6. Further information on whether the IVF clinics encouraged patients to donate embryos.

I my Summary Letter I wrote: "Patient [who] consented [to using their] embryos for research were consulted on research activity with the embryos and were not offered any inducement for the donation."

In my previous Response to ACD Committee I wrote: "...as seen from Sample consents for frozen embryos, patients had the following choices: to continue storage, to discard embryos, to donate embryos for scientific research or to attempt to donate to another infertile couple. **It was also clearly stated that patients may refuse and their future treatment would not be affected**. Further, patients were told that they would no longer have access to their specimens once donated".

~~In the letter of [redacted] IRB Chair [redacted] M.D. it is written:~~
~~"...There will be no financial compensation of any type for this donation..."~~

Not part of 12/9/10 presentation

7. Whether any financial arrangements existed between the IVF clinics and CMRC.

~~In the letter of [redacted] IRB Chair [redacted] M.D. it is written:~~
~~"...There will be no financial compensation of any type for this donation..."~~

Not part of 12/9/10 presentation

Here I attest that no financial arrangements existed between the IVF clinics and CMRC. My correspondence is CCed to the CMRC Signing Official.

Please help me to clarify what exactly is needed to assure a positive decision of ACD Committee.

1. We would need a statement from IVF director of MFC regarding donated fresh embryos with a description:

- Time of donations, procedures used e.g. PGD and quality of embryos;
- Possibly redacted consents;
- Statements: that no financial compensation was offered to the patients and whether donors were given more specific information orally about the nature of the hESC research. Anything else?

~~2. We do not need the statement form [redacted] IVF director, providing the input from [redacted] IRB letter and the supporting documentation, ... or we do need it? What then should be confirmed?~~

Not part of 12/9/10 presentation

Thank you for your help.

Vasil Galat

Name	ICM isolation	Embryo Stag	Feeder source	Serum substitut	PGD	Caryotype	Mutations	Published
CM2	microsurgery	blastocyst	MEF	SR	FISH	46, XX	duplication on chromosome 4	1
CM6	microsurgery	blastocyst	MEF	SR	FISH	46, XX		1
CM7	microsurgery	blastocyst	HFF (human)	SR	FISH	46, XX		1, 2

1 L. C. Laurent, C. M. Nievergelt, C. Lynch, E. Fakunle, J. Harness, U. Schmidt, V. Galat, A. L. Laslett, T. Otonkoski, H. Keirstead, A. Schork, H-S. Park, J. F. Loring Restricted Ethnic Diversity in Human Embryonic Stem Cells. Nature Methods. 2010. 1 (7). 6-7. PMID: 20038950

2 Malchenko S, V. Galat, E. A. Seftor, E. F. Vanin, R. E.B. Seftor, M. B. Soares and M. J.C. Hendrix. Cancer Hallmarks in Induced Pluripotent Cells: New Insights. Journal of Cellular Physiology. 2010. 225; 2; 390-393. PMID: 20568225 (COVER)